GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2267
ANSWERED ON:29.07.2016
Exemption on Clinical Trials
K. Shri Parasuraman;Vellaigounder Shri Elumalai

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government proposes to relax the norms exempting academic institutions to conduct clinical trials and need to get prior approvals of the Drug Controller General of India;

(b) if so, the details thereof;

(c) whether the Government is concerned about the possibilities for misuse of this exemption; and

(d) if so, the details thereof and the corrective actions taken by the Government in this regard?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)

(a) & (b): The Government has vide GSR No.313 (E) dated 16.03.2016 amended the Drugs and Cosmetics Rules, 1945 to inter alia provide as below:
"no permission for conduct of clinical trial intended for academic purposes in respect of approved drug formulation shall be required for any new indication or new route of administration or new dose or new dosage form where,-
(a) the trial is approved by the Ethics Committee; and
(b) the data generated is not intended for submission to licensing authority.
The Ethics Committee shall, however, inform the licensing authority about the cases approved by it and also about cases where there could be an overlap between the clinical trial for academic and regulatory purposes and where the said authority does not convey its comments to the Ethics Committee within a period of thirty days from the date of receipt of communication from the Ethics Committee, it shall be presumed that no permission from the licensing authority is required."

(c) & (d): Sufficient provisions exist in the Drugs & Cosmetics Act, 1940 and the Rules, thereunder to deal with any case of misuse or non-compliance with any of the provisions of the Act and the rules.